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What we'll cover:



NIH Data Management and Sharing (DMS) Policy



Preparing DMS plans



Exceptions and responsible management and sharing



Budgeting



Form H requirements



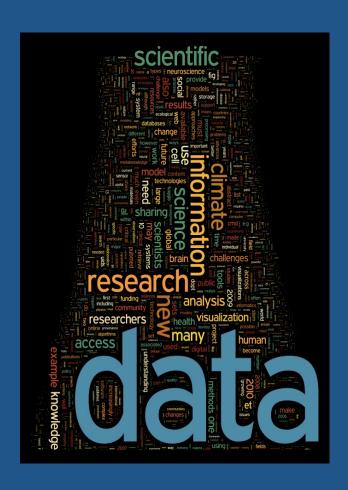
How to get help



NIH has a longstanding commitment to making the results of research available.

The new Data Management and Sharing Policy creates a consistent minimum expectation for all research supported by agency.

NIH Policy Notice NOT-OD-21-013 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html



DMS Policy: Scope

Applies to <u>all</u> research, funded or conducted in whole or in part by NIH, that results in the generation of "scientific data".

"Scientific data" is defined as:

"the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."

Potential Examples of Scientific Data

Scientific data will vary depending on the project and the context.

Scientific data might include:

Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS

Electrophysiological recordings and fMRI images in a study of a rodent model of PTSD

Step activity from a wearable device in a study of cardiovascular health

from the DMS Policy

Scientific data do not include:

- Data **not** necessary for or of sufficient quality to validate and replicate research findings,
- Laboratory notebooks,
- Preliminary analyses,
- Completed case report forms,
- Drafts of scientific papers,
- Plans for future research,
- Peer reviews,
- Communications with colleagues, or
- Physical objects, (e.g., laboratory specimens)

Activities Subject to the DMS Policy

APPLIES TO...

All research generating scientific data, including but not limited to:

- Research Projects
- Certain Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

DOES NOT APPLY TO...

research projects <u>not</u> generating scientific data or non-research projects, including but not limited to:

- Training (Ts)
- Fellowships (Fs)
- Certain non-research Career Awards (e.g., KM1)
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)



Policy Effective Dates

The DMS Policy applies to all NIH funding mechanisms

Extramural	Competing applications submitted for Jan 25, 2023, and subsequent receipt dates - Non-competing awards will not immediately become subject to Policy
Contracts	Proposals submitted on or after Jan 25, 2023
Intramural	Projects conducted on or after Jan 25, 2023
Other funding agreements (e.g., Other Transactions)	Executed on or after Jan 25, 2023, unless otherwise stipulated by NIH

Policy Requirements

 Submission of Data Management & Sharing Plan with all covered funding applications for beginning January 25, 2023

2. Compliance with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office for the life of the award

Limitations on Sharing

DMS Plans should maximize appropriate sharing

Justifiable ethical, legal, and technical factors for limiting sharing include:

- Informed consent will not permit or limit scope of sharing or use
- Privacy or safety of research participants would be compromised and available protections insufficient
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- Restrictions imposed by existing or anticipated agreements with other parties

See Protecting Privacy When Sharing Human Research Participant Data for additional details

Limitations on Sharing: Other Considerations

Reasons NOT generally justifiable to limit sharing:

- Data are considered too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository

Elements of a DMS Plan



Data type

Identifying data to be preserved and shared

Related tools, software, code

Tools and software needed to access and manipulate data

Standards

Standards to be applied to scientific data and metadata

Data preservation, access, timelines

 Repository to be used, persistent unique identifier, and when/ how long data will be available

Access, distribution, reuse considerations

Description of factors for data access,

See Writing a Data Management & Sharing Plan for details

snaring

Plan compliance will be monitored/ managed and by whom



Format of a DMS Plan

- ✓ Plans should be no more than 2 pages in length
- Optional format page is available

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing nih.gov. The Plan is recommended not to exceed two pages. Text in italies should be deleted.

Element 1: Data Type

- A. Types and amount of scientific data expected to be generated in the project: Summarize the types and estimated amount of scientific data expected to be generated in the project.
- B. Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.
- C. Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data

Element 2: Related Tools. Software and/or Code:

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they

See <u>DRAFT Data Management and Sharing Plan</u> for optional template

DMS Plan Submission

- A new "Other Plan(s)" field will be added to the PHS 398 Research Plan form to collect a single PDF attachment
- Data Sharing Plans and Genomic Data Sharing Plans will no longer be submitted to the "Resource Sharing Plan(s)" field

Research Plan Section			
5. Vertebrate Animals	Add Attachment	Delete Attachment	View Attachment
3. Select Agent Research	Add Attachment	Delete Attachment	View Attachment
7. Multiple PD/PI Leadership Plan	Add Attachment	Delete Attachment	View Attachment
3. Consortium/Contractual Arrangements	Add Attachment	Delete Attachment	View Attachment
9. Letters of Support	Add Attachment	Delete Attachment	View Attachment
10. Resource Sharing Plan(s)	Add Attachment	Delete Attachment	View Attachment
11. Other Plan(s)	Add Attachment	Delete Attachment	View Attachment
 Authentication of Key Biological and/or Chemical Resources 	Add Attachment	Delete Attachment	View Attachment

See FORMS H: PHS 398 Research Plan for additional details

Sharing Data

Encourages use of established repositories

Depositing data in a quality repository generally improves the FAIRness of data – Findable, Accessible, Interoperable, Reusable

NIH ICs may designate specific data repository(ies)

See <u>Selecting a Data Repository</u> for details

Finding and Selecting a Repository: Desirable Characteristics for All Data Repositories

- ✓ Unique Persistent Identifiers
- ✓ Long-Term Sustainability
- Metadata
- Curation and Quality Assurance
- ✓ Free and Easy Access
- ✓ Broad and Measured Reuse

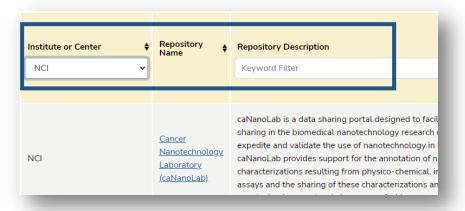
- ✓ Clear Use Guidance
- ✓ Security and Integrity
- Confidentiality
- ✓ Common Format
- ✓ Provenance
- ✓ Retention Policy



Finding and Selecting a Repository: NIH & Other Resources

NIH-Supported Repositories

Filterable list of 70+ NIH Repositories



Other Repository Resources

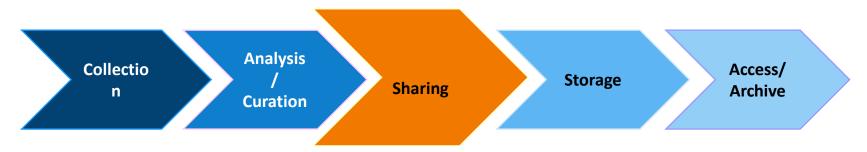
- Generalist repositories
- Nature's Data Repository
 Guidance
- Registry of Research Data Repositories

See Repositories for Sharing Scientific Data

When should I share my data?

As soon as possible!

No later than the time of a **publication of findings** in a peerreviewed journal OR at the **end of the award**, whichever comes first



Data Management and Sharing Costs

ALLOWABLE COSTS:

- Curating data/developing supporting documentation
- Preserving/sharing data through repositories
- Local data management considerations
- **IMPORTANT:** Must be incurred during the performance period

UNALLOWABLE COSTS:

- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

Submitting DMS Budgets

- Direct costs to support the activities proposed in the DMS Plan must be indicated as "Data Management and Sharing Costs"
 - R&R Budget Form: line item in section F. Other Direct Costs

F. (Other Direct Costs	Funds Requested (\$)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Data Management and Sharing Costs	
9.		
10.		

PHS 398 Modular Budget Form: within Additional Narrative Justification

2. Budget Justifications						
	Personnel Justification			Add Attachment	Delete Attachment	View Attachment
	Consortium Justification			Add Attachment	Delete Attachment	View Attachment
	Additional Narrative Justification			Add Attachment	Delete Attachment	View Attachment



Justifying DMS Budgets

- Brief summary of DMS Plan and description of DMS costs must be included within the budget justification attachment
 - R&R Budget Form: section L. Budget Justification

L. Budget Justification						
(Only attach one file.)		Add Attachment	Delete Attachment	View Attachment		

PHS 398 Modular Budget Form: Additional Narrative Justification

2. Budget Justifications						
	Personnel Justification		Add Attachment	Delete Attachment	View Attachment	
	Consortium Justification		Add Attachment	Delete Attachment	View Attachment	
	Additional Narrative Justification		Add Attachment	Delete Attachment	View Attachment	

DMS Plan Assessment



- NIH Institute & Center staff will determine if DMS Plan is acceptable or unacceptable
- Peer reviewers ONLY consider if the budget is reasonable. Comments from the peer reviewers regarding reasonableness will not affect the score.

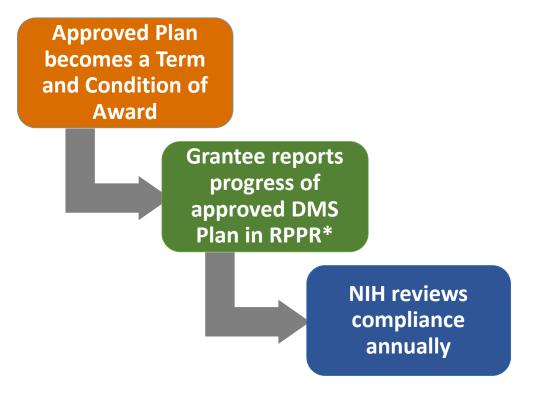
Resolving Issues Before Award

- DMS Plan must be approved prior to NIH making an award
- If additional details are needed, it may be necessary to communicate with NIH staff to resolve issues with DMS Plan
 - Will occur through standard Just-In-Time (JIT) process
 - Provide additional information and potentially a revised DMS Plan
 - Work with your assigned Grant & Contract Officer to respond to such requests

Monitoring Compliance



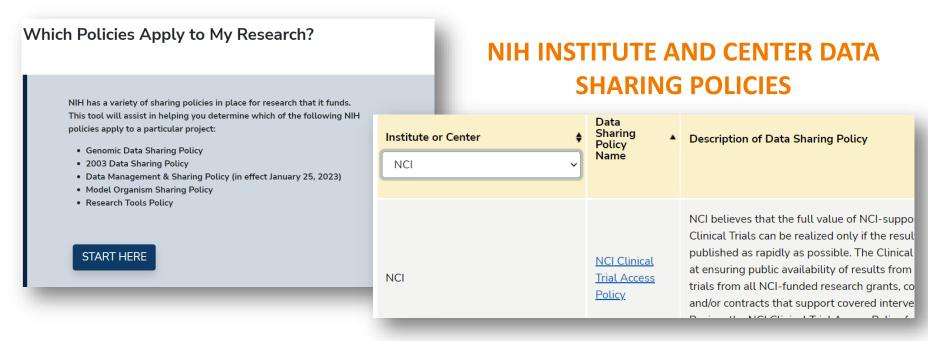
*RPPR: Research Performance Progress Report (RPPR) - Annual, Interim, and Final



Failure to comply.... may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

Is my research also subject to other NIH data sharing policies?

DECISION TOOL



FDP DMS Demonstration Pilot Project

- Collaboration between the Federal Demonstration
 Partnership (FDP) membership, NIH Office of Policy for
 Extramural Research Administration (OPERA), NIH Institutes &
 Centers, and Open Education Resources groups.
- Goals of the DMS Demonstration Pilot:
 - Generate greater consistency in DMS Plan requirements across NIH ICs and programs.
 - Mitigate the administrative burden for researcher associated with DMS Plan development and implementation.
- Expected to run 9/1/2022 12/31/2023



FDP Pilot Timeline

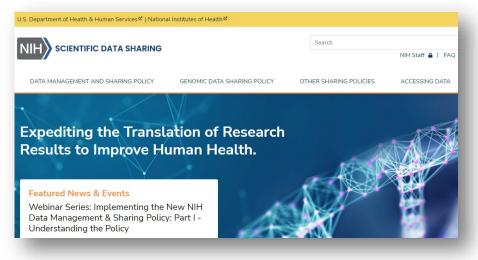
Phase 1: Test Standardized DMS Plan Templates and DMPTool – 12/22-12/23

• Pilot participants will test the effectiveness of new web-based (DMPTool) templates to support the generation of a DMS Plan that is compliant with the new NIH policy and meets the varying needs of ICs.

Phase 2: Cost Policies – 1/23-12/23

- Establish common cost principles.
- Identify types of costs required.
- Determining how to identify additional/unforeseen costs that may be required to meet the spirit of the data sharing policy.

For More Information...



- Website: NIH Scientific Data Sharing
- FAQs: DMS Policy FAQs
- Email Box: Sharing@nih.gov
- Webinar Part II: <u>Diving Deeper</u> into the New NIH <u>Data</u> <u>Management and Sharing Policy</u>

For More Information...

Policy References:

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NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing
NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
NOT-OD-22-189- Implementation Details for the NIH Data Management and Sharing Policy
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NOT-OD-22-198 – Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023



Cornell Support



eCommons

- Public access
- Persistent identifiers
 (Handle, DOI)
- Flexible, optional licenses
- Curatorial review DCN member
- Links to and citations for related materials
- Versioning
- Long-term sharing and preservation

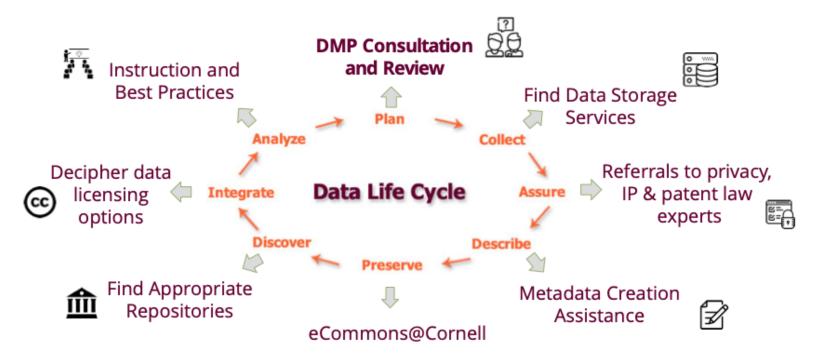




100,140 items in eCommons

Cornell Research Data Management Service Group

http://data.research.cornell.edu/





Stay in the loop!



Join the RDMSG mailing list Visit the RDMSG website Email the RDMSG with questions



